

## REMARKS

### **A. Background**

Claims 14-51 were pending in the application at the time of the Office Action with claims 16, 17, 25, 33-37, 41, 44, 49, and 51 being withdrawn from consideration. The Office Action rejected claims 14, 15, 18-24, 26-28, 32, 38, 40, 46, and 47 as being anticipated by cited art. Claims 42, 43, and 45 were rejected as being obvious over cited art. Claims 29-31, 39, 48, and 50 were objected to as being dependent upon a rejected base claim. By this response Applicant has amended claims 14, 26, 30, 31, 38, 49 and 50; cancelled claims 22, 29, 32-37 and 48; and added new claims 55-63. As such, claims 14-21, 23-28, 30, 31, 38-47, 49-51, and 55-63 are presented for the Examiner's consideration in light of the following remarks with claims 16, 17, 25, 41, 44, 49, and 51 being withdrawn from consideration.

### **B. Proposed Claim Amendments**

The claims have been amended to further clarify the invention. Applicant respectfully submits that the amendments to the claims and the new claims are supported by the specification and drawings as originally filed, and more specifically by at least Figures 12A-C and 17. Accordingly, Applicant submits that the claim amendments do not add new matter and entry of the amendments is respectfully requested.

### **C. Rejection on the Merits**

#### **35 U.S.C. 102 Rejections**

Applicant respectfully notes that a claim is anticipated under 35 U.S.C. § 102(a), (b), or (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

single prior art reference. Further, the identical invention must be shown in as complete detail as is contained in the claim. Finally, the elements must be arranged as required by the claim. MPEP § 2131

Pages 2 and 3 of the Office Action reject claims 14, 18-20, 22, 26-28, and 32 under 35 US C § 102(b) as being anticipated by U.S. Patent No. 5,019,103 to Van Zile et al. Applicant has herein cancelled claims 22 and 32, thus making the rejection moot regarding these claims. Regarding the rest of the rejected claims, in view of amendments made herein Applicant respectfully traverses this rejection.

Van Zile teaches a modular prosthetic system for mounting a variety of styles of wedges to a tibial tray to correct for bone deficiencies. See Van Zile Abstract. As shown in Figures 1 and 3, cannulated screws 48 are inserted through a tray 22 and screwed into a wedge 46 to secure wedge 46 to tray 22. See col. 5, lines 57-68. Once wedge 46 and tray 22 are secured together, bone screws 50 are then received through the bores of cannulated screws 48 and screwed into the proximal end of the tibia to secure the system to the bone. See col. 6, lines 14-20. A male stem 36 can also extend down from tray 22 and be received within a female stem 39 that has been implanted into the bone for added stability. See col. 5, lines 13-20.

The Office Action equates cannulated screw 48 and bone screw 50 of Van Zile with the “stem” and “fastener”, respectively, of the invention as recited in claims 14 and 26. However, because cannulated screw 48 in Van Zile is separate from tray 22 and must be screwed into tray 22 and wedge 46, Van Zile does not teach or suggest “the bearing plate and the stem comprising a unitary member that is fabricated from a single piece of material,” as recited in amended claim 14. Furthermore, because cannulated screw 48 in Van Zile is used to fasten wedge 46 to tray 22, Applicant asserts that it would not be obvious to modify Van Zile to make cannulated screw 48 a unitary member with tray 22. If screw 48 were a unitary member with tray 22, screw 48 would not

be able to be rotated and would not function to secure wedge 46 to tray 22. This would force wedge 46 to have to be pre-secured to tray 22, necessarily forcing only one style of wedge 46 to be used with each tray 22. Because the purpose of Van Zile is to allow different styles of wedges to be mounted to a tibial tray to correct for bone deficiencies, this would render the Van Zile prosthetic system unsatisfactory for its intended purpose.

Regarding claim 26, because bone screw 50 of Van Zile is not encircled by anything except the cannulated screw 48, which the Office Action equates to the “stem” of the invention as recited in claim 26, Van Zile does not teach or suggest a stem, a fastener, and “a tubular bone anchor removably encircling at least a portion of the fastener,” as recited in amended claim 26. Thus, independent claims 14 and 26 are distinguished over Van Zile.

Claims 18-20, 27, and 28 depend from one of claims 14 or 26 and thus incorporate the limitations thereof. As such, applicant submits that each of these dependent claims is also distinguished over the cited art for at least the same reasons as discussed above with regard to claims 14 and 26. As such, withdrawal of the anticipation rejection of claims 14, 18-20, and 26-28 is respectfully requested

Page 3 of the Office Action rejects claims 14, 21-24, 26-28, 38, 46, and 47 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 6,102,954 to Albrektsson et al. Applicant has herein cancelled claim 22, thus making the rejection moot regarding this claim. Regarding the rest of the rejected claims, in view of amendments made herein Applicant respectfully traverses this rejection.

As seen in Figure 6, Albrektsson teaches a prosthesis for replacement of a tibial side of a knee joint, including a plate 30 that is placed on the bone. Before plate 30 is placed on the bone, a screw fixture 20 having a threaded bore is secured within the bone and a horizontal channel is cut in the bone. Plate 30 has a horizontal tube-like fixture element 31 corresponding to the horizontal

channel. Plate 30 is then placed on the bone by sliding fixture element 31 into the channel until a hole 22 within plate 30 aligns with the bore of screw fixture 20. A screw 21 is then inserted through hole 22 and screwed into the bore of screw fixture 20 to secure plate 30 to the bone.

The Office Action equates screw fixture 20 and screw 21 of Albrektsson with the “stem” and “fastener”, respectively, of the invention as recited in claims 14 and 26. However, because screw fixture 20 in Albrektsson is separate from plate 30 and must first be inserted into the bone, Albrektsson does not teach or suggest “the bearing plate and the stem comprising a unitary member that is fabricated from a single piece of material,” as recited in amended claim 14. Furthermore, because fixture element 31 of Albrektsson must first be slid into the horizontal channel before hole 22 within plate 30 can align with the bore of screw fixture 20, Applicant asserts that it would not be obvious to modify Albrektsson to make screw fixture 20 a unitary member with plate 30. By so doing, screw fixture 20 would hit against the bone and prevent fixture element 31 from sliding into the horizontal channel, thus rendering the Albrektsson prosthesis unsatisfactory for its intended purpose.

Regarding claim 26, because screw 21 of Albrektsson is not encircled by anything except screw fixture 20, which the Office Action equates to the “stem” of the invention as recited in claim 26, Albrektsson does not teach or suggest a stem, a fastener, *and* “a tubular bone anchor removably encircling at least a portion of the fastener,” as recited in amended claim 26. Finally, claim 38 has been amended to include the limitations of claim 48, which the Office Action conceded would be allowable subject matter (see below). Thus, independent claims 14, 26, and 38 are distinguished over Albrektsson.

Claims 21, 23, 24, 27, 28, 46, and 47 depend from one of claims 14, 26, or 38 and thus incorporate the limitations thereof. As such, applicant submits that each of these dependent claims is

also distinguished over the cited art for at least the same reasons as discussed above with regard to claims 14, 26, and 38. As such, withdrawal of the anticipation rejection of claims 14, 21, 23, 24, 26-28, 38, 46, and 47 is respectfully requested.

Page 3 of the Office Action also rejects claims 14, 15, 22, 26, 27, 38, 40, and 46 under 35 USC § 102(e) as being anticipated by U.S. Publication No. 2004/0106928 to Ek.<sup>1</sup> Applicant has herein cancelled claim 22, thus making the rejection moot regarding this claim. Regarding the rest of the rejected claims, in view of the amendments made herein Applicant respectfully traverses this rejection.

As seen in Figure 7, Ek teaches a condylar implant 130 including an angled bearing surface 20, an intermediate mount 21 and a fixation element 22, all initially separated from one another. Bearing surface 20 and intermediate mount 21 are press-fit together and mounted on fixation element 22. Fixation element 22 has external helical threads that allow fixation element 22 to be screwed into the bone from below.

The Office Action equates intermediate mount 21 and the fixation element 22 of Ek with the “stem” and “fastener”, respectively, of the invention as recited in claims 14 and 26. However, because intermediate mount 21 in Ek is initially separated from bearing surface 20, Ek does not teach or suggest “the bearing plate and the stem comprising a unitary member that is fabricated from a single piece of material,” as recited in amended claim 14. Regarding claim 26, because fixation element 22 of Ek is not encircled by anything except bone, Ek does not teach or suggest a stem, a fastener, and “a tubular bone anchor removably encircling at least a portion of the fastener,” as recited in amended claim 26. Finally, claim 38 has been amended to include the limitations of claim

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<sup>1</sup> Because Ek is only citable under 35 U.S.C. § 102(e), Applicant does not admit that Ek is in fact prior art to the claimed invention but reserves the right to swear behind Ek if necessary to remove it as a reference.

48, which the Office Action conceded would be allowable subject matter (see below). Thus, independent claims 14, 26, and 38 are distinguished over Ek.

Claims 15, 27, 40, and 46 depend from one of claims 14, 26, or 38 and thus incorporate the limitations thereof. As such, applicant submits that each of these dependent claims is also distinguished over the cited art for at least the same reasons as discussed above with regard to claims 14, 26, and 38. As such, withdrawal of the anticipation rejection of claims 14, 15, 26, 27, 38, 40, and 46 is respectfully requested.

### **35 U.S.C. 103 Rejections**

Page 4 of the Office Action rejects claims 42, 43, and 45 under 35 USC § 103(a) as being unpatentable over the Albrektsson patent in view of the Van Zile patent. Specifically, the Office Action asserts that Albrektsson does not disclose “a pocket and an inlay having a porous bone ingrowth material, a fastener having a length in a range between about 5mm to about 15mm and an enlarged crown nut removably mountable to the fastener,” and that it would have been obvious to include these items based on the teachings of Van Zile.

As mentioned previously, claim 38 has been amended to include the limitations of claim 48, which the Office Action conceded would be allowable subject matter (see below). As such, applicant submits that claim 38 is allowable for at least the same reason that claim 48 was considered allowable in the Office Action. Claims 42, 43, and 45 depend from claim 38 and thus incorporate the limitations thereof. As such, applicant submits that each of these dependent claims is allowable for at least the same reason that amended claim 38 is allowable. As such, withdrawal of the rejection of claims 42, 43, and 45 is respectfully requested.

### **Allowable Subject Matter**

Page 5 of the Office Action objects to claims 29-31, 39, 48, and 50 as being dependent upon a rejected base claim but states that the claims would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Regarding claims 29-31: Claim 29 has been cancelled herein and claim 26, from which claim 29 previously depended, has been rewritten in independent form to incorporate the limitations set forth in claim 29. As a result, applicant asserts that claim 26 is in allowable form. Claims 27, 28, 30, and 31 depend from claim 26 and thus incorporate the limitations thereof. As such, Applicant respectfully submits that each of these dependent claims is also in condition for allowance for at least the same reasons as discussed above with regard to claim 26.

Regarding claim 39: Applicant has added new claim 55, which is previous claim 39 rewritten in independent form to incorporate the limitations set forth in claims 38 and 39. As a result, applicant asserts that claim 55 is in allowable form. New claims 56-58 depend from claim 55 and thus incorporate the limitations thereof. As such, Applicant respectfully submits that each of these dependent claims is also in condition for allowance for at least the same reasons as discussed above with regard to claim 55.

Regarding claims 48 and 50: Claim 48 has been cancelled herein and claim 38, from which claim 48 previously depended, has been rewritten to incorporate the limitations set forth in claim 48. As a result, applicant asserts that claim 38 is in allowable form. Claims 39-51 depend from claim 38 and thus incorporate the limitations thereof. As such, Applicant respectfully submits that each of these dependent claims is also in condition for allowance for at least the same reasons as discussed above with regard to claim 38.

### **New Claim Distinctions**

Applicant has added new claims 59-63 and submits that the new claims are distinguished over the cited art because the cited art neither singularly nor in combination with one another includes each and every element of any of the claims. For example, none of the cited art teach

an elongated fastener having a first end and an opposing second end, the first end being removably mounted to the bottom surface of the bearing plate without extending through the bearing plate; and a nut having a passage extending completely therethrough, the nut being removably threaded onto the fastener from the second end of the fastener,

as recited in claim 59, or

a fastener comprising an elongated shaft having a first end and an opposing second end, the first end being removably mounted to the bottom surface of the bearing plate, an enlarged head being permanently fixed on the shaft or an enlarged nut being removably mountable onto the shaft; and a tubular bone anchor removably encircling at least a portion of the fastener,

as recited in claim 62.

Claims 60-61 depend from claim 59 and thus incorporate the limitations thereof. Claim 63 depends from claim 18 and thus incorporates the limitations thereof. As such, Applicant respectfully submits that each of these dependent claims is also not anticipated for at least the same reasons as discussed above with regard to claims 59 and 18.

No other objections or rejections are set forth in the Office Action.

### **D. Conclusion**

Applicant notes that this response does not discuss every reason why the claims of the present application are distinguished over the cited art. Most notably, applicant submits that many if not all of the dependent claims are independently distinguishable over the cited art. Applicant has merely submitted those arguments which it considers sufficient to clearly distinguish the claims over the cited art.

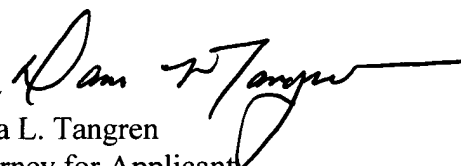


In view of the foregoing, applicant respectfully requests the Examiner's reconsideration and allowance of claims 14-21, 23-28, 30, 31, 38-47, 49-51, and 55-63 as amended and presented herein.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Dated this 30 day of January 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Dana L. Tangren", with a long horizontal flourish extending to the right.

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